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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,180	01/05/2005	Hisao Nishikawa	029650-162	7679

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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07/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,180

Applicant(s)

NISHIKAWA ET AL.

Examiner

Laura A. Bouchelle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 7-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 7-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/21/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 3, 4, 5, 19, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (US 4781691) in view of Melker (US 5242410). Gross discloses a stepped needle comprising a liquid container 40 capable of holding liquid therein; an injection needle 10 having a puncture section 20 capable of piercing a living body; a proximal end section 14 having outside and inside diameters greater than said puncture section; a tapered section 18; a base body 12 supporting the needle, wherein the tapered section and the puncture section protrude from the base body. The tapered section 18 facilitates passage of the needle through the body tissue (Col. 4, lines 29) See Figs. 2 and 6. Gross further discloses that the injection needle has a liquid introducing needle section that can communicate with the liquid container. See Fig. 2. The outside diameter of the proximal end 14 is 0.64-1.3 mm, the outside diameter of the puncture section 16 is 0.46-0.64 mm, the length from the puncture section to the tapered section is 6.4-19 mm (Col. 3, line 63 – Col. 4, line 8). The puncture resistance is inherently 7gf or less since the device has the same size and shape as applicant's.
3. Claims 1 and 4 differ from Gross in calling for the taper to have an angle ranging from 0.5 degree to 1.2 degrees. Melker teaches a dilator having a taper from the distal end 5 to the

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transition point 6 having an angle in the range from about 1.26 degrees to about 5.18 degrees.

This taper provides a suitable degree of gentle entry into a vessel (Col. 4, lines 27-35). See Fig.

1. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the needle of Gross to have a taper of about 1.26 degrees as taught by Melker to provide a suitable degree of gentle entry into a vessel. Although Melker teaches a dilator and applicant's invention is drawn to a needle, both are elongate tubes that pass through the skin into the body, and it is the examiner's position that providing gentle entry into the vessel is the same as providing smaller puncture resistance.

4. Claims 7, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Melker as applied to claims 1, 4 above, and further in view of Hardt et al (US 5575778). Claim 7 differs from the teachings above in calling for the proximal end of the needle to include a second needle point. Hardt teaches a syringe having a needle 26 having a point at both the proximal and distal ends so that the proximal end of the needle can be inserted through the sealed septum of a container. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the needle of Gross in view of Melker to have a second point on the proximal end so that the needle can be inserted into a sealed container.

5. Claims 8-11, 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Melker as applied to claims 1, 4 above, and further in view of Peery (US 7063681). These claims differ from the teachings above in calling for the puncture section to comprise a first facet having an angle of 8.5 degrees and a second facet having an angle of 18 degrees.

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Peery teaches a puncturing device having a puncture section 40 having a first facet having an angle of 5-45 degrees and a second facet having an angle of 10-60 degrees to provide minimal tissue trauma during insertion (Col. 4, lines 55-61; Col. 5, lines 7-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Gross in view of Melker to include the two facets as taught by Peery to reduce tissue trauma upon insertion.

6. Claims 12, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Melker as applied to claims 1, 4 above, and further in view of Kaneko et al (US 6517523). Claims 12, 18 differ from the teachings above in calling for the cross-sectional angle formed between the ridges of the needle point to be 129 degrees. Kaneko teaches a needle comprising a pointed tip having a cross-sectional angle formed between the ridges to be 115-135 degrees to ensure that the resistance force at the time of sticking is as small as possible (Col. 6, lines 45-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the needle of Gross in view of Melker to include a cross-sectional angle of 129 degrees as taught by Kaneko to ensure that the resistance force at the time of sticking is as small as possible.

Response to Arguments

7. Applicant's arguments filed 4/16/07 have been fully considered but they are not persuasive.

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8. Applicant argues that Gross and Melker do not teach the tapered section as claimed. It is believed that the combination of Gross in view of Melker does teach the invention as claimed. Gross is silent as to the degree of the tapered section. Melker teaches the required degree of taper to allow the member to be easily inserted into a puncture site. Furthermore, in applicant's specification, applicant clearly contemplates other ranges for the degree of taper in the tapered section, and therefore, it is clear that the claimed range is not critical. One of ordinary skill in the art would know that having a taper of a smaller angle would inherently reduce the force required to insert that tapered portion into a puncture site in the skin. For all the reasons above, it is believed that this claim is anticipated by the prior art.

9. Applicant argues that the device of Gross is not disclosed as puncturing the skin. The device of Gross is clearly capable of puncturing the skin as it has a sharp beveled tip.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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